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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,150	11/17/2006	Nicole Dominique Hussey	0641-0273PUS1	3977

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EXAMINER
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CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

NOTIFICATION DATE	DELIVERY MODE
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03/20/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,150	<b>Applicant(s)</b> HUSSEY ET AL.	
	<b>Examiner</b> Suryaprabha Chunduru	<b>Art Unit</b> 1637	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 February 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 125-147 is/are pending in the application.
- 4a) Of the above claim(s) 133-138 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 125-132 and 139-147 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/29/05; 7/12/07; 8/22/07; 10/24/08</u>                       | 6) <input type="checkbox"/> Other: _____                          |



**DETAILED ACTION**

1. Applicant's election with traverse of Group I (claims 125-132 and 139-147) in the reply filed on February 17, 2009 is acknowledged. The traversal is on the ground(s) that the prior art cited by EPO search Authority does not anticipate newly added claim 125, since the prior art (Fiegler et al.) cited as X category reference in International preliminary report does not break the unity of the invention. The arguments were found unpersuasive because the lack of unity was based on the X references cited in the EPO search report that anticipates the original claims 1-6, 11-16, 19-35, 40-45, 48-58, and 104-108 and Examiner notes the amendment cancels original claims 1-124 and added new claims 125-147, in which claim 125 incorporates all the limitations from the original claim 1 and its dependent claim 2, which were anticipated by the prior art cited by the EPO search report. Thus it is noted that mere cancellation of original claims and adding new claims, would not change the scope of the claims and the prior art as cited does anticipate the new independent claim 125, that represents original canceled claims 1-2. Accordingly the lack of unity is still deemed proper.

***Status***

2. Claims 125-132, and 139-147 are considered for examination and claims. Claims 133-138 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group.

***Priority***

3. This application filed on November 17, 2006 is a 371 of PCT/AU04/00429 filed on 4/02/2004 and claims Foreign priority to AUSTRALIA 2003901671 filed on 4/02/03.

***Information Disclosure Statement***

4. The Information Disclosure Statement filed on 9/29/05, 7/12/07, 8/22/07 and 10/24/08 have been considered and acknowledged.

***Informalities***

5. The following informalities are noted:

(i) claim 127 recites improper Markush group. It would have been 'selected from the group consisting of'.

(ii) claims 126-132 and 140-147 recite 'A method according to'. It would have been 'The method according to'.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 127, and 141 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claim recites a group of repetitive sequences. The meets and bounds of the claims are unclear and indefinite because it is unclear whether the claims require all the recited repetitive sequences or any one of the sequences. Amendment to recite a proper markush group is advised.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 125-132, 139-141, 145-147 are rejected under 35 U.S.C. 102(a) as being anticipated by Fiegler et al. (Genes, Chromosomes & Cancer, Vol. 36, No.4, pp. 361-374, April 2003, published on line January 30, 2003).

Fiegler et al. teach a method of claims 125, 139, comparing at least one chromosome or part thereof from a cell with a first karyotype with the corresponding chromosome or part thereof from a cell with a second karyotype, comprising

- (a) randomly amplifying DNA from an isolated chromosome or part thereof, the amplified DNA being depleted of repetitive sequences (see at least page 362, col. 2, paragraph 3, page 363, col. 1, paragraph 1-2, col. 2, paragraph 1-3, page 364, col. 1, paragraph 2);

- (b) attaching the amplified DNA to a solid substrate (see page 363, col. 2, paragraph 3);

- (c) amplifying DNA from one or more cells (less than 100 cells) with a first karyotype (male) and amplifying DNA from one or more cells from a second karyotype (female) (see page 362, col. 2, paragraph 2, page 364, col. 1, paragraph 1, col. 2, line 5-13 of the paragraph 2);

- (d) labeling the amplified DNA of the first karyotype with a first label and amplified DNA of the second karyotype with a second label (see page 364, line 5-13 of the paragraph 2);

- (e) hybridizing the amplified and labeled DNA from the first and the second karyotype with the amplified DNA attached to the solid substrate (see page 364, col. 2, paragraph 2, page 365, col. 1, line 1-15, col. 2, paragraph 2);

(f) comparing relative amount of first and second labels hybridized to the amplified DNA attached to the solid substrate (see page 366, col. 2, line 6-110, page 367, col. 1, paragraph 1, col. 2, line 1-9, page 368, col. 1, line 1-12).page 372, col. 2, paragraph 1).

With regard to claims 126, 140, Fiegler et al. teach that the part of an isolated chromosome is a clone fragment of a chromosome (see page 362, col. 2, paragraph 3).

With regard to claims 127, 141, Fiegler et al. teach that the repetitive sequences include cot-1 sequences (see page 364, col. 1, paragraph 2).

With regard to claim 128, Fiegler et al. teach that the amplification of DNA from cells with first and second karyotype comprises randomly primed amplification (see page 364, col. 2, paragraph 2).

With regard to claim 129, Fiegler et al. teach that the first karyotype comprises DNA amplified from one cell (see page 364, col. 2, paragraph 2).

With regard to claims 130-132, 145-147, Fiegler et al. teach that the method comprises cancerous cells and the method for detecting a chromosomal abnormality (deletion) in the cell (see page 367, col. 1, paragraph 1). Accordingly the claims are anticipated.

B. Claims 125-132, 139-147 are rejected under 35 U.S.C. 102(b) as being anticipated by Hussey et al. (WO 00/24925).

Hussey et al. teach a method of claims 125, 139, comparing at least one chromosome or part thereof from a cell with a first karyotype with the corresponding chromosome or part thereof from a cell with a second karyotype, comprising

(a) randomly amplifying DNA from an isolated chromosome or part thereof, the amplified DNA being depleted of repetitive sequences (see at least page 4, line 23-35, page 5, line 1-14, page 13, line 18-27);

(b) attaching the amplified DNA to a solid substrate (see page 6, line 8-18);

(c ) amplifying DNA from one cell (less than 100 cells) with a first karyotype (unknown) and amplifying DNA from one cell from a second karyotype (known) (see page 2, line 28-34);

(d) labeling the amplified DNA of the first karyotype with a first label and amplified DNA of the second karyotype with a second label (see page 3, line 1-3);

(e) hybridizing the amplified and labeled DNA from the first and the second karyotype with the amplified DNA attached to the solid substrate (see page 3, line 4-6).

(f) comparing relative amount of first and second labels hybridized to the amplified DNA attached to the solid substrate (see page 3, line 7-9).

With regard to claims 126, 140, Hussey et al. teach that the part of an isolated chromosome is a clone fragment of a chromosome (see page 362, col. 2, paragraph 3).

With regard to claims 127, 141, Hussey et al. teach that the repetitive sequences include cot-1 sequences (see page 13, line 18-27).

With regard to claim 128, Hussey et al. teach that the amplification of DNA from cells with first and second karyotype comprises randomly primed amplification (see page 5, line 6-14, page 12, line 9-25).

With regard to claim 129, 142, Hussey et al. teach that the first karyotype comprises DNA amplified from one cell (see page 12, line 9-25).



With regard to claims 130-132, 145-147, Hussey et al. teach that the method comprises pre-implantation embryonic cells, fetal cells and the method for detecting a chromosomal abnormality (extra chromosome) in the cell (see page 3, line 14-29, page 15, line 17-22).

With regard to claims 143, Hussey et al. teach that the method comprises lysing the cells with a first karyotype and the random amplification DNA resulting from the lysis occur in the same tube (see page 12, line 9-25).

With regard to claim 144, Hussey et al. teach that the method includes the step of performing further round of random amplification of the randomly amplified DNA from the cells with the first karyotype and labeling the DNA with a first label concurrently with or after the further round of random amplification (see page 5, line 6-34). Accordingly the claims are anticipated.

### ***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637